



Mike.Teague@clariant.com

04/26/2006 08:36 AM

To Kimberly Tisa/R1/USEPA/US@EPA

cc Marianne Milette/R1/USEPA/US@EPA, Tom
Olivier/R1/USEPA/US@EPA, Erin.Russell@clariant.com,
John.Paul@clariant.com, js1@bbl-inc.com

bcc

Subject Re: RA Addendum - Comments

Kim -

Clariant recognizes we owe you a response, and we've been working with BBL to finalize it. We've got a couple of remaining issues with a vapor pressure calculation about which the Clariant site is providing input to BBL. Once those issues are addressed, we should be able to ship you what we've got. Due to scheduling issues this week for our technical people in Coventry, BBL won't get the extra detail until next week, and then they'll need to process it, update the response and send it to us for final review. It may be a couple more weeks before we can get it to you. Sorry it's taking longer than expected.

Thanks.

Mike

Mike Teague
Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205 USA
Office Phone: 704.331.7104
Cell Phone: 704.904.8707
FAX: 704.330.1528

tisa.kimberly@epamail.epa.gov

04/21/2006 09:39 AM

To Mike.Teague@clariant.com

cc millette.marianne@epamail.epa.gov, olivier.tom@epamail.epa.gov

Subject Re: RA Addendum - Comments

Mike-

I'm following up with you re: Clariant. I believe tis was the last correspondence you sent me wrt the status of your response to Versar's 12/16/2005 comments. Please advise.

Just as an aside, I believe I had supplied comments to John Paul re:

Clariant's proposed re-processing plans back in September 2005. Do you know what the status of Clariant's response to this is?

Kimberly N. Tisa, PCB Coordinator (CPT)
U.S. Environmental Protection Agency
1 Congress Street, Suite 1100
Boston, MA 02114-2023

phone: 617.918.1527
fax: 617.918.0527
e-mail: tisa.kimberly@epa.gov

Mike.Teague@clar
iant.com

12/20/2005 03:40
PM

Kimberly Tisa/R1/USEPA/US@EPA

To
cc

Subject
Re: RA Addendum - Comments

Hi Kim -

Just to confirm that I received your email with the latest Versar comments and to let you know that I've forwarded them to John Schell at BBL. After today, I'm out of the office until January 2, but John said he would be around to go over Versar's comments and formulate a draft opinion and response. We'll get back with you after the first of the year to discuss next steps.

Happy Holidays!

Mike

Mike Teague
Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205 USA
Office Phone: 704.331.7104
Cell Phone: 704.904.8707
FAX: 704.330.1528



MEMORANDUM

TO: Laura Casey
FROM: Diane Sinkowski, Mike Koontz
DATE: August 1, 2005
SUBJECT: Review of Clariant/BBL Response to Versar Request for Additional Information/Calculations (June 20, 2005)

cc: 11.1126.2000.001
Jim Buchert

Per your technical directive (July 11, 2005), Versar has reviewed Clariant's response to Versar's request to provide additional calculations showing the relative contributions of different exposure routes (ingestion, dermal absorption, and inhalation) to the total dose estimates. The requested information was provided by Clariant in an Excel spreadsheet named "forward calcs2_7.5.xls". Additionally, the spreadsheet included risk-based carpet concentrations based on a retention factor (RF) of 1.0, where all the PCBs in the carpeting are volatilized. The calculations now present a range of bioavailability factors (BioAFs) and RFs that include the worst-case scenario of a BioAF of 1.0 and an RF of 1.0. All the calculations have been verified (an example is provided in Attachment 1). The only problem found with the calculations is that the weekly air exchange rate (AE) used, 126, is noted as being based on an hourly AE rate of 0.35/hr, but is actually based on the original higher AE rate of 0.75/hr. The weekly AE rate based on 0.35/hr would be 58.8. During our conference call on June 16th, it was agreed that a lower AE of 0.35/hr or, at the very least, the typical or average value of 0.45 AEs per hour, as given in the *Exposure Factors Handbook*, corresponding to a weekly AE of 75.6 should be used. The risk-based carpet concentrations for an AE of 0.75 provided in the spreadsheet are shown in Table 1. The target total PCB carpet concentrations associated with an AE of 0.35/hr are presented in Table 2.

From a comparison of Tables 1 and 2, it is apparent that changing the AE rate from 0.75/hr to 0.35/hr makes a substantial difference only when the RF is 1.0. With an RF of 1.0, the inhalation route accounts for more than half of the total lifetime cancer risk and the total hazard index (see the above-referenced spreadsheet). To obtain some insight on an appropriate value for the RF, we performed an alternative calculation using a mass-balance approach, calculating a steady-state or average concentration in lieu of that calculated using the volatilization factor. For the mass-balance approach, it was assumed that all tPCB mass in the carpet was released, at a constant rate, over its 10-year lifetime (details on the calculation can be provided on request). The results from the two approaches were similar only if a larger value (in the range of 0.1 to 1.0) was used for the RF when making the calculation using the volatilization factor.

As discussed in the conference call, there is a high degree of uncertainty associated with the oral BioAF and, especially, the RF. Although in reality it is probable that ingested PCBs are not all bioavailable, EPA has not yet reviewed the available data and provided a recommendation. Similarly, some amount of PCBs may be retained in the carpeting, although, as discussed in the uncertainty section of the April 11, 2005, submission, some empirical data exist. Some assumed exposure parameters do introduce conservatism to the calculations. Such assumptions include a child exposure for 350 days a year for 10 years or a carpet fiber ingestion rate of 55 mg/day. Ideally, a small-chamber test for a time period such as 30 days to fit a time-varying emission profile to the data should be conducted. This profile then could be used as a basis for estimating the fraction of tPCBs in the carpet that ultimately would be emitted over its 10-year life.

Additionally, if a BioAF and an RF, other than the worst-case scenario is to be assumed, the target risk could be modified to a lower (i.e., more stringent) value as a safety factor.

Please feel free to contact us if you have any questions.

$$\text{Inhalation} = (\text{Conc} * \text{IHR} * 1/\text{VF} * \text{RF} * \text{ED} * \text{EF}) / (\text{ATnc} * \text{BW}) / \text{RfD}$$

Parameter	Value	Explanation
Conc	133	Carpet concentration (mg/kg) (multiply by 0.000001 to get kg/kg or fraction)
IHR	10.42	Inhalation rate (m ³ /day)
VF (m ³ /kg) = $[d_w(m) * 10^{3.83-0.62 \log V_p}] / [\text{Mass}_c(\text{mg}/\text{m}^2) / 1000000 (\text{mg}/\text{kg})] / \text{AE} = 137745.1$		
RF	0.001	Retention Factor (unitless)
ED	10	Exposure duration (carpet life; yrs)
EF	350	Exposure frequency (days/yr)
ATnc	3650	Averaging time for noncarcinogens (days)
BW	21.8	Body weight (children 6 months to 12 yrs old; kg)
RfD	0.00002	Reference Dose

$$\text{HQ} = (133 * 10.42 * 1/137745.1 * 0.001 * 10 * 350) / (3650 * 21.8) / 0.00002 = 0.022 \text{ or } 2.2\text{E-}02$$



Kimberly Tisa/R1/USEPA/US

10/12/2005 04:21 PM

To Mike.Teague@clariant.com

cc Erin.Russell@clariant.com, js1@bbl-inc.com

bcc Marianne Milette/R1/USEPA/US

Subject Re: Revised Assessment Table and Versar Comments 

Mike-

I left you a voice message regarding data quality and have also discussed this with John. Given that we're trying to make a determination on the carpet, I need to insure that the data is of sound quality and that we're using the appropriate inputs.

In addition, I had received comments from Versar in August regarding the revised calculations provided by you on June 20, 2005. I was waiting for the updated PCB concentrations before providing the comments to you. I have reviewed the Addenda (which incorporates the revised PCB data). Based on this review, I am providing Versar's comments to you and ask that you check the calculations in the Addenda to insure they are accurate and correct. If not, please let me know and I will hold the Addenda and wait for revision before sending to Versar.

Please call me if you have any questions.



Review of Clariant Calculations 08012005.wpd

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
1 CONGRESS STREET, SUITE 1100
BOSTON, MASSACHUSETTS 02114-2023

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Receipt No: 7002 0860 0000 6598 0836

September 29, 2005

John Paul, ESHA Manager
Clariant Corporation
500 Washington Street
Coventry, Rhode Island 02816

Re: Application for Re-Processing of PCB-Contaminated Pigments

Dear Mr. Paul:

This is in response to the Clariant Corporation (Clariant) *Application to Rework PCB-Contaminated Pigment Product*, dated June 27, 2005 and received by EPA on July 7, 2005 (Application). This Application was submitted by Clariant to support its process for the re-processing of contaminated pigments containing PCBs greater than 50 parts per million (> 50 ppm) which were inadvertently generated during manufacturing.

EPA has reviewed the Application and provides the following comments.

1. The title page contains the designation "Attorney-Client Privilege Confidential Business Information"; Section 1 inventory page contains the designation "TSCA Confidential Information". It is unclear if Clariant is claiming this Application as TSCA Confidential Business Information (CBI) or is claiming just CBI. For any submittal that is claimed TSCA CBI, you must clearly identify the portions that are claimed TSCA CBI, include two sanitized versions and address the submittal to the Document Control Officer (Rosina Toscano, mailcode SEP) directly. Please be aware that a claim of TSCA CBI for certain portions of the Application may be problematic, especially for evaluation of analytical methodology. Accordingly, Clariant may wish to consider claiming certain portions (such as inventory) TSCA CBI, and the remainder as CBI under 40 CFR Section 2.203b. If you wish to claim some or all of the information you submit as CBI, you must follow the procedures described in EPA's regulations at 40 C.F.R. Part 2, Subpart B.
2. Clariant has provided insufficient information for EPA's evaluation of the process design. Section 5 contains a simplified process flow chart procedure for reworking the contaminated pigments. However, EPA finds the procedure difficult to follow and is unable in many cases to find the steps referenced in the procedure. It would be helpful if Clariant could provide a schematic of the system design.

3. Flow Diagram, Section 5. There are 2 pathways for solvent recovery; one pathway indicates PCB contaminated solvent and the other pathway shows clean solvent.
 - a. For the 1st pathway, it appears that this is the pathway for the distilled PCBs from the slurry solution. It is unclear what the distillation temperature is and if it is satisfactory for the PCB congeners of interest.
 - b. The second pathway indicates clean solvent, which may be a misnomer. In the procedure, there appears to be a PCB maximum limit for the clean solvent of 3 ppm. If so, the solvent is not technically "clean" as is inferred in the diagram.
4. The analytical method (Section 6) for the proposed project is Clariant Method GC001.
 - a. EPA cannot fully evaluate this method as the GC001-Addendum 1 for standard preparation was not included in the Application.
 - b. Step 5.4.1.2, last paragraph. The step refers to addition of anhydrous sodium sulfate for removal of sulfuric acid. Please note that this explanation is slightly misleading. The sodium sulfate will remove **water** from the solution. Since the water contains the sulfuric acid, it will be removed with the water.
 - c. The method proposes GC calibration using 3 tetrachlorobiphenyl (TCB) standards: The only data presented in the Application reported the PCBs as "total PCBs" and did not include the specific congeners identified. As such, EPA can make no determination on the adequacy of the selected calibration standards.
 - d. The method contained no information on calibration procedures or on data quality and method evaluation.
5. Page 3 of the narrative (schedule discussion) refers to reworking of pigment material containing < 50 ppm and that all results have been successful. Clariant should include any information pertaining to this reworking in this Application. For example, a discussion of the materials reworked, the procedure employed, and the pre- and post-reworking PCB analytical results should be included.

As a point of clarification, please be aware that a Consent Agreement and Final Order (CAFO) will need to be executed to return PCB-contaminated product from Mexico for purposes of "reworking". In addition, since the PCB-contaminated product currently stored at Clariant is unauthorized, the CAFO must be executed and include a reference to the Application or any workplan approved by EPA prior to "reworking" of this product.

Should you have any questions, please feel free to call me at (617) 918-1527.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly N. Tisa". The signature is fluid and cursive, with the first name being more prominent.

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection/Chemical Management Branch

cc: ✓ M. Milette, EPA
T. Olivier, EPA



MEMORANDUM

TO: Laura Casey
cc: Jim Buchert
FROM: Mike Koontz/Diane Sinkowski
11.1126.1000.001.01
DATE: June 6, 2005
SUBJECT: Review of "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (April 11, 2005)

As requested, Versar has reviewed the revised calculations provided in the April 11, 2005, Clariant report. Remaining issues that should be addressed or discussed are as follows:

1. Without supporting information, such as laboratory studies or direct measurements, on PCB retention in carpeting, Table 3 should include calculations of acceptable PCB concentrations assuming additional retention factors, including a worst-case retention factor of 100 percent (i.e., 1.0).
2. We are not comfortable with the inclusion of the assumed air exchange rate of 126 air exchanges per week into the Bennet and Furtaw equation calculating the volatilization factor (VF) (see Equations 5 through 7, pages 2-3 and 2-4). In particular, the use of a weekly value seems somewhat arbitrary and the units (air exchanges per week) do not produce the appropriate units for VF (m^3/kg), as demonstrated below.

The value for VF can be determined from the following relationship, given as Equation 7 in the report:

$$VF = (d_w * 10^{3.82 - 0.62 \log VP} * AE) / FW$$

Equation 7, page 2-4

Where:

d_w = carpet thickness in m,
VP = vapor pressure in Pa,
AE = air exchanges per week, and
FW = carpet face weight in kg/m^2 .

Using 0.01286 m for d_w , 0.0069 Pa for VP, 126/week for AE, and 1.7 kg/m^2 for FW, as given in the report, we get the following value for VF:

$$VF = [(0.01286 \text{ m}) * (10^{3.82 - 0.62 \log (0.0069 \text{ Pa})}) * (126/\text{week})] / 1.7 \text{ kg}/\text{m}^2 = 137,745 \text{ m}^3/\text{kg-week}$$

The calculated value for VF is not presented in the report, so the resulting units are not

presented. However, VF, as used in Equations 1, 7, and 9, must have units of m^3/kg . Thus, further justification of this calculation is necessary.

Please feel free to contact us at 703-750-3000 x 737 if you have any questions or comments.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
1 Congress Street, Suite 1100
BOSTON, MA 02114-2023

CERTIFIED MAIL

March 21, 2005

Michael A. Teague, Ph.D.
Vice President / ESHA
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Re: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap
Scenarios Associated with Pigment Red 144/214, February 2005

Dear Dr. Teague:

This is in response to your *February 2005 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214*. EPA's contractor, Versar, has completed its review of this submittal. Versar's comments are attached.

EPA expects Clariant to make any necessary revisions to the comprehensive assessments as soon as possible. Accordingly, EPA requests that Clariant provide its estimated schedule for completion of the revised assessments within 7 days of receipt of this letter.

Should you have any questions, please call me at (617) 918-1527 or by e-mail at tisa.kimberly@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly N. Tisa".

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection

cc: T. Olivier, EPA
M. Milette, EPA

attachment



MEMORANDUM

TO: Laura Casey cc: 11.1126.1000.001.01
FROM: Diane Sinkowski, Jim Buchert
DATE: March 18, 2005
SUBJECT: Review of "Exposure and Screening-level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" (February 2005)

I have reviewed the revised risk assessment and response to comments provided by Clariant, per the technical direction provided by EPA Region 1 on February 24, 2005, and have the following comments:

1. The volatilization factor, VF, calculated in this assessment is presented with the units of kg/m^3 . A unit analysis of 3 of the equations seems to contradict this.
 - In Equations 1 and 9, the VF needs to be in units of m^3/kg , so that the inhalation factor can be added to the other factors in the denominator, which are in kg^2/mg . This yields the correct units for the PCB concentration in carpeting, $\text{CNC}_{\text{carpet}}$ of mg/kg .
 - In Equation 8, if the units of Cg are mg/m^3 , and the units of M are mg/kg , then the units of VF need to be m^3/kg .
2. Where does room surface area fit into these calculations? Is a certain area incorporated in the empirical equation used (Equation 2)? Typically, when an air concentration is calculated from soil or groundwater, the area of the source needs to be known and is incorporated into the calculation because a larger area results in a higher concentration.

Please feel free to contact me if you have any questions.

MEMORANDUM

To: Mr. Jim Buchert, Versar, Inc.
From: Laura Casey, OPPT/NPCD/FOB
RE: Technical Direction to Work Assignment 0-1
Subject: Clariant Corporation, Coventry, Rhode Island

EPA-Region 1 has received from the Clariant Corporation its response to Versar's January 23, 2005 comments on the *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios* dated December 6, 2004 (*Exposure Assessment*) associated with Clariant's Red Pigments. Clariant has also provided a revised *Exposure Assessment* incorporating Versar's comments, as applicable. EPA will provide both the response and the revised *Exposure Assessment* to Versar under separate cover.

Please review these documents for the following:

- Please review the response and the revised *Exposure Assessment* and determine if Clariant has adequately addressed Versar's comments.

Due Date: Please turn the review of these documents around by **March 17, 2005**. If there are any questions regarding this due date, please contact me at 202-566-1982.

Technical questions relating to this project may be addressed directly to Kim Tisa in Region 1 at 617-918-1527 or by e-mail at tisa.kimberly@epa.gov.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
1 Congress Street, Suite 1100
BOSTON, MA 02114-2023

CERTIFIED MAIL

January 25, 2005

Michael A. Teague, Ph.D.
Vice President / ESHA
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Re: Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap
Scenarios Associated with Pigment Red 144/214, December 6, 2004

Dear Dr. Teague:

This is in response to your *December 6, 2004 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214*. EPA's contractor, Versar, has completed its review of this submittal. Versar's comments are attached.

EPA expects Clariant to make any necessary revisions to the comprehensive assessments as soon as possible. Accordingly, EPA requests that Clariant provide its estimated schedule for completion of the revised assessments within 7 days of receipt of this letter.

Should you have any questions, please call me at (617) 918-1527 or by e-mail at tisa.kimberly@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly N. Tisa", is written over the typed name.

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection

cc: T. Olivier, EPA
M. Milette, EPA

attachment



MEMORANDUM

TO: Laura Casey
cc: Jim Buchert
11.1126.1000.001.01

FROM: Diane Sinkowski

DATE: January 23, 2005

SUBJECT: Review of "Exposure and Screening-level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214"(December 6, 2004)

I have reviewed the submitted risk assessment and have provided, below, comments addressing the items specified by EPA in the technical direction provided by Region 1 on 12/20/04.

1. Does the *Exposure Assessment* consider all pathways for the uses included in the assessment? If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

The pathways considered seem appropriate for the exposure scenarios evaluated.

2. Were Versar's October 25, 2004 comments adequately addressed in the *Exposure Assessment*? If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

Versar's previous comments have been adequately addressed.

3. Are there areas where data gaps exist and where additional information is required? Versar shall identify any data deficiencies, and if found, provide possible resolutions such as (but not limited to) the collection of additional samples or requesting additional information.

- On page 2-5, the risk assessment indicates that a soil dust ingestion rate of 55 mg per day was assumed for children and is based on data from Moya et al. (2004). I was unable to find this value in the cited reference. The Moya et al. reference states the following:

Children's mean soil ingestion values ranged from 39 mg/day to 271 mg/day with an average of 138 mg/day for soil ingestion and 193 mg/day for soil and dust ingestion. Upper percentile values average 358 mg/day for soil and 790 mg/day for soil and dust combined.

Could Clariant please provide clarification on the origin of the assumed value?

- Clariant should provide information regarding exposure frequency and duration for the food wrap scenario and revise the calculations shown at the bottom of page 3-2 accordingly, since the calculations only reflect one day's consumption of cheese. In particular, for carcinogenic risk, the calculated daily dose shown, 0.0000014 mg tPCBs/kg BW/day, cannot be compared to the target lifetime average daily dose of 0.000014 mg/kg BW/day (Table 1) without dividing by the lifetime averaging time (i.e., 25,550 days).
- Table 1 (page 7-1) of the risk assessment indicates that a slope factor of $0.07 \text{ (mg/kg-d)}^{-1}$ was assumed for calculating the cancer risk from ingestion, dermal absorption, and inhalation of PCBs. The value is the upper-bound slope factor for PCBs of the lowest risk and persistence. EPA's criteria for use of this slope factor (www.epa.gov/iris/subst/0294.htm) is that congener or isomer analyses verify that congeners with more than 4 chlorines comprise less than 1/2% (0.5%) of total PCBs. Page 1-2 (bottom paragraph) of the risk assessment indicates that PCB congeners 44 and 70 make up approximately 90 percent of the total PCBs found in Pigment Red 144 and 214. It is uncertain from this statement whether the additional PCB congeners in the pigments are of low chlorine content. Clariant should demonstrate to EPA that the composition of the pigments meets EPA's criteria for use of the $0.07 \text{ (mg/kg-d)}^{-1}$ slope factor.
- 4. Are the formulas provided in the *Exposure Assessment* appropriate and are the proposed exposure/risk model input parameters correct? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.
- According to the risk assessment, Equation 4 (page 2-3) is obtained by substituting Equation 3 into Equation 2 (both on page 2-2), and solving for C_g (room air concentration of tPCB vapor). Equation 4 (without the parameter "D") is as follows:

$$C_g = \left(\frac{d_w \times 10^{3.83-0.62 \times \log VP}}{M} \right)$$

However, as shown in the steps below, the substitution has not been performed correctly:

$$\text{Given: } K_{SA} = \frac{k_s}{k_d} = 10^{3.82-0.62 \times \log VP}$$

and

$$K_{eq} = \frac{k_s}{k_d} = \frac{M}{C_g}$$

Substituting for $\frac{k_s}{k_d}$:

$$K_{SA} = \frac{\frac{M}{C_g}}{d_w} = 10^{3.82-0.62 \times \log VP}$$

Rearranging to solve for C_g :

$$C_g = \frac{\frac{M}{d_w}}{10^{3.82-0.62 \times \log VP}} = \frac{M}{d_w \times 10^{3.82-0.62 \times \log VP}}$$

This correction should be made and any calculations performed using this equation should be revised.

- The parameter M, as defined in the risk assessment, is incorrect. Table 1 (page 7-1) of the risk assessment indicates that M is the carpet area mass (face weight; mg/m²). The parameter M, as defined in the Bennett and Furtaw (2004) and the Won, et al. (2000) papers, is the mass of the compound [PCBs] collected on the sink [carpeting] per unit area (mg/m²). Therefore, the value shown in Table 1 for the carpet area mass and the calculated air concentration in an enclosed space 7 days post installation of a new carpet are incorrect, unless Clariant means to assume that the entire mass of the carpet is tPCBs.
- Equation 5 from the risk assessment (see below), has parameters representing the tPCB concentration in the carpeting (CC_{Carpet}) and the concentration in the air (C_g). There cannot be two concentration parameters in the equation. When a unit analysis is done, one can see that the ingestion and dermal absorption parameters cancel to mg/kg as they should, since the equation is being solved for CC_{Carpet} which is in units of mg/kg. However, when the units for the inhalation contribution to the equation are canceled, the term is unitless instead of being mg/kg. Equation 5 and the calculations for CC_{Carpet} should be revised.

$$CC_{\text{carpet}} = \frac{TR \times BW \times AT_c}{ED \times EF \times \left[\left(\frac{CSF \times IR \times BioAF}{10^6 \text{ mg/kg}} \right) + \left(\frac{CSF \times SA \times AF \times DERM}{10^6 \text{ mg/kg}} \right) + (CSF \times IHR \times C_s \times VRF) \right]}$$

$$CC_{\text{carpet}} \text{ (inhalation term only)} \left(\frac{\text{mg}}{\text{kg}} \right) = \frac{TR \times BW \times AT_c}{ED \times EF \times (CSF \times IHR \times C_s \times VRF)} = \frac{(-) \times (\text{kg}) \times (\text{days})}{(\text{yr}) \times \left(\frac{\text{days}}{\text{yr}} \right) \times \left(\frac{\text{mg}}{\text{kg-day}} \right)^{-1} \times \left(\frac{\text{m}^3}{\text{day}} \right) \times \left(\frac{\text{mg}}{\text{m}^3} \right) \times (-)} = (-)$$

- A volatilization rate factor, VRF, is included in the inhalation exposure calculation. However, since the equation from the Bennett and Furtaw (2004) paper, already takes into account desorption of the compound (tPCBs) from the sink material (carpeting), a VRF should not be included in the calculation if the methodology from the Bennet and Furtaw paper is to be used to calculate a tPCB air concentration.
- A bioavailability factor, (assumed values were 1, 5, 10, 50, and 100%, see Table 1), was included in the calculation of the ingestion dose. Although EPA has studied and provided some guidance regarding the relative bioavailability of metals, such as lead, at this time, U.S. EPA has not provided guidance for PCBs. Until EPA reviews all the studies on PCBs and comes to a consensus regarding the relative bioavailability of PCBs in soil, no bioavailability factors should be included when calculating PCB intakes via the ingestion pathway.

Please contact me if there are any questions regarding these comments or if additional information is needed.

Clariant Corporation

4000 Monroe Road
Charlotte, NC 28205
704.331.7000

Via FedEx

November 8, 2004

Kimberly Tisa, PCB Coordinator (CPT)
USEPA
1 Congress Street, Suite 1100
Boston, MA 02114-2023

**RE: Red Pigment Project
Comprehensive Assessments**

Dear Ms. Tisa:

Clariant has received your response dated October 26, 2004 concerning the Conceptual Exposure Model / Preliminary Assessment ("CEM") dated August 31, 2004. You have asked for an estimated schedule for completion of the comprehensive risk assessments. As documented in the CEM, Clariant has determined that the end use which poses the highest exposure potential is carpet fiber. Clariant will submit to you a report of the quantitative risk assessment of exposure to carpet fibers no later than December 6, 2004.

The two comments on the CEM raised by Versar included in your October 26 response will be addressed by the forthcoming document.

If you have any questions or need additional information, please feel free to contact me at 704-331-7104.

Sincerely,

CLARIANT CORPORATION



Michael A. Teague, Ph.D.
Vice President / ESHA

Enclosure

cc: Erin Russell, Esq.
John Schell, Ph.D.
John Paul
Robert Freet, Ph.D.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
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BOSTON, MA 02114-2023

CERTIFIED MAIL

October 26, 2004

Michael A. Teague, Ph.D.
Vice President / ESHA
Clariant Corporation
4000 Monroe Road
Charlotte, North Carolina 28205

Re: Conceptual Exposure Model and Preliminary Assessment for End Users of Pigment Red
144 and 214, August 31, 2004

Dear Dr. Teague:

This is in response to your August 31, 2004 submittal which defines a Conceptual Exposure Model for assessing potential exposure risks associated with the use of Clariant Pigments Red 144 and 214.

EPA's contractor, Versar, has completed its review of this submittal. Versar's comments are attached. While the Conceptual Exposure Model appears thorough and no substantial omissions were identified, Versar's comments must be incorporated into the comprehensive risk assessments.

Given that no major revisions to the Exposure Model appear to be needed, EPA expects Clariant to proceed as soon as possible with the comprehensive assessments. Accordingly, EPA requests that Clariant provide its estimated schedule for completion of these assessments within 7 days of receipt of this letter.

Should you have any questions, please call me at (617) 918-1527 or by e-mail at tisa.kimberly@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kimberly N. Tisa".

Kimberly N. Tisa, PCB Coordinator
Office of Ecosystem Protection

cc: T. Olivier, EPA
M. Milete, EPA

attachment



MEMORANDUM

TO: Laura Casey cc: James Buchert
1126.1000.001.01 file

FROM: Diane Sinkowski

DATE: October 25, 2004

SUBJECT: Review of *Conceptual Exposure Model and preliminary Assessment for Endocrine Disruptors in Cosmetics* (August 31, 2004)
Users of Pigment Red 144 and 214 (August 31, 2004)

I have reviewed the submitted assessment approach and exposure route and pathway dendograms. The diagrams provide a thorough preliminary estimate of the potential pathways associated with exposure to PCBs in industrial and consumer end-use products.

I just have the following brief comments:

- The dendrograms show that for consumers, exposure to PCBs could potentially occur from skin contact with and ingestion of PCBs found in surface dust. I want to make certain that, the exposure assessment considers the transfer of PCBs embedded in the material that are available at the surface of a manufactured item to skin contacting that surface. (A material does not necessarily have to produce particulates (i.e., dust) to have PCBs become available.) Similar to surface dust, some of the available PCBs in the material that adhere to the skin are inadvertently ingested from hand-to-mouth activity.
- Also, if releases from production activities are found to affect soil, then inhalation of fugitive dust should be considered as an exposure pathway.

Please call if you have any questions or need additional information.



MEMORANDUM

TO: Laura Casey
FROM: Diane Sinkowski
DATE: October 25, 2004
SUBJECT: Review of *Conceptual Exposure Model and preliminary Assessment for End Users of Pigment Red 144 and 214* (August 31, 2004)
cc: James Buchert
1126.1000.001.01 file

I have reviewed the submitted assessment approach and exposure route and pathway dendograms. The diagrams provide a thorough preliminary estimate of the potential pathways associated with exposure to PCBs in industrial and consumer end-use products.

I just have the following brief comments:

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- Also, if releases from production activities are found to affect soil, then inhalation of fugitive dust should be considered as an exposure pathway.

Please call if you have any questions or need additional information.

Risk Conceptual Exposure Model [Summarized]
+ App Vol 1 & 2 in King's files.

CBI [CEM] in CBI work



Laura Casey
10/04/04 09:46 AM

To: Marianne Millette/R1/USEPA/US@EPA
cc:
Subject: Fw: Clariant Work Plan

FYI - Versar received the Clariant package.

Laura

----- Forwarded by Laura Casey/DC/USEPA/US on 10/04/04 09:46 AM -----



Diane Sinkowski
<DSinkowski@versar.com>
10/04/04 09:29 AM

To: Laura Casey/DC/USEPA/US@EPA
cc: James Buchert <BUCHEJAM@versar.com>
Subject: Re: Fw: Clariant Work Plan

Hi Laura,

I did receive the package.

Didi

>>> <Casey.Laura@epamail.epa.gov> 10/04/04 07:34AM >>>

Good morning

Please let Marianne and I know ASAP if you do not receive this material.

Thanks

Laura

----- Forwarded by Laura Casey/DC/USEPA/US on 10/04/04 07:33 AM -----

Kimberly Tisa

Casey/DC/USEPA/US@EPA
09/30/04 04:52 PM
Millette/R1/USEPA/US@EPA, Tom

To: Laura
cc: Marianne
Olivier/R1/USEPA/US@EPA
Subject: Clariant Work

Plan

Laura-

Just to let you know, I received confirmation from Clariant that the Work Plan was sent to VERSAR today via FEDEX ...Tracking # 791351322646.

Please let VERSAR know. If for any reason they don't receive it, they should contact Marianne so that she can followup with Clariant.

Thanks!

Kimberly Tisa, PCB Coordinator (CPT)
USEPA
1 Congress Street, Suite 1100
Boston, MA 02114-2023

617.918.1527 (PHONE)
617.918.0527 (FAX)
e-mail: tisa.kimberly@epa.gov



Mike.Teague@clariant
.com

10/01/04 07:45 AM

To: Kimberly Tisa/R1/USEPA/US@EPA
cc: Laura Casey/DC/USEPA/US@EPA, Marianne
Milette/R1/USEPA/US@EPA, Tom Olivier/R1/USEPA/US@EPA,
Erin.Russell@clariant.com
Subject: Re: Conceptual Exposure Model Work Plan - Revised Directions

Kim:

As we discussed yesterday, your email had not arrived by 4 PM even though you sent it at 2:43 PM (it arrived sometime after 6:15 PM when I left the office). I did indeed ship to Versar, at the address you gave me over the phone, the referenced documents via FedEx yesterday (tracking number 791351322646). I faxed you a copy of the transmittal letter. Versar should expect to see the documents today. If they do not, please contact me.

Thank you.

Mike

Mike Teague
Vice President, ESHA
Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205 USA
Office Phone: 704.331.7104
Cell Phone: 704.904.8707
FAX: 704.330.1528

tisa.kimberly@epam
ail.epa.gov
erin.russell@clariant.com, mike.teague@clariant.com
olivier.tom@epamail.epa.gov, milette.marianne@epamail.epa.gov,
09/30/2004 02:43
PM
Model Work Plan - Revised Directions
To:
cc:
Casey.Laura@epamail.epa.gov
Subject: Conceptual Exposure

Please ignore my previous message. Given the clarification by Mike Teague on the dendograms, Clariant should do the following:

Send a copy of the entire Work Plan to VERSAR, which includes the following:

- Sanitized version of the Conceptual Exposure Model
- Appendix Volume 1
- Appendix Volume 2

Please insure that the CEM is the sanitized version as VERSAR CANNOT accept any CBI.

The Work Plan should be sent to the following via FEDEX:

VERSAR, Inc.
Attn: Diane Sinkowski
6850 Versar Center
Springfield, VA 22151

It is my understanding that the Work Plan will be shipped to VERSAR today (September 30). Please confirm via e-mail that the Work Plan was shipped today or let us know when it did/will be sent. Again this is important so that VERSAR and the Work Assignment Manager know the WP is coming.

Should you have any questions after today, please call Marianne as I will be on annual leave until October 18.

Kimberly Tisa, PCB Coordinator (CPT)
USEPA
1 Congress Street, Suite 1100
Boston, MA 02114-2023

617.918.1527 (PHONE)
617.918.0527 (FAX)
e-mail: tisa.kimberly@epa.gov